IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Manuela GUGLIELMO et al. Conf. 8261

Application No. 10/537,296 Group 1619

Filed June 2, 2005 Examiner B. Gulledge

PREPARATION FOR TOPICAL USE WITH THE FUNCTION OF COMBATING HAIR LOSS

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Daniela MONTANARI, one of the inventors of the above identified application do hereby declare:

I am a Biologist, head of the Research & Development Department of Labo Europa located in Padova, Italy. My curriculum vitae are attached herewith.

I am familiar with the present application, and I have reviewed the outstanding Official Action of May 26, 2009. In doing so, I have reviewed the written description rejection of claims 11-14 and the obviousness rejection of claims 8-14 over DESJONQUERES, HIRAMA et al., and ZAVERI et al. The Official Action appears not to appreciate the unexpected and superior results achieved by the claimed invention.

In order to show the unexpected and superior results achieved by the synergistic effect of the combined elements at

their specific concentrations I have supervised the following lab tests:

1. Effectiveness (against hair loss) test for a composition comprising Octylbutyrate plus glutaminpeptide: Composition A.

2. Effectiveness (against hair loss) test for the claimed composition comprising Octylbutyrate plus glutaminpeptide, monomethylsilanol-hydroxyproline aspartate, benzyl nicotinate, and panthenol: Composition B.

3. Comparison between Test 1 and Test 2, showing the superior effect of composition B vs. composition A.

1. Effectiveness lab test on (Composition A)

To determine the effectiveness against hair loss of a specified composition, i.e. lotion, Applicants used the method called phototrichogram to analyze the behavior of the hair in terms of number of units on a surface and the distribution of the percentage of hairs in anagen and telogen phase:

20 male subjects were selected with hair loss problems aged between 18 and 60 years. In a defined area of the scalp of about 5 mm^2, Applicants cut the hair and took digital pictures of the area in order to count the number of hair. After 3 days, pictures were taken of the cut area.

Subsequently, the 20 volunteers received a hair lotion to be applied for 3 months, every day, about 5 ml of lotion by massaging without a rinse. 9 subjects received a placebo, and the other 9 received a lotion containing only

0.03% by weight of Octylbutyrate + 0.03% by weight of glutaminpeptide as active ingredients (Composition A).

The distribution of lotions (placebo or lotion) was done at random, without informing the volunteer.

After 3 months of treatment, the same area is shaved and photographed and photographed again, 3 days after shaving.

A comparison of images between D0 and D3 and those between D90 and D93 makes it possible to determine the total number of hair and the number of hairs in anagen and telogen phase.

Before the start of treatment and at the end of the year, the volunteers complete a questionnaire on self-produced and treatment.

The following table summarizes the results:

Average number if hair Of the shaved area (5 mm^2)				
	D0		D90	
	Telogen Phase	Anagen Phase	Telogen Phase	Anagen Phase
Treatment*	11.22	38.33	7.89	42.22
Placebo	6.33	43.56	5.22 **-29.7%**	45.11 **10.15%**

The numbers in bold refer respectively to the percentage reduction of hair in telogen phase and increasing percentage of hairs in anagen phase resulting from the treatment.

* Lotion containing only Octylbutyrate + Glutaminpeptide as active substances.

It is noted that in 8 out of 9 cases (89%), the number of hairs in the anagen phase significantly increases. The number of hairs in telogen phase decreases in 7 cases out of 9 (average decrease of hair in telogen phase, 30 %).

The changes after use of placebo lotion are not significant.

The analysis of completed questionnaires from the volunteers leads to the following observations:

- Treatment group*:
  - The importance of hair loss is strong for 22% of the volunteers, average 67% and close to 11%.
  - After 3 months of treatment with the lotion treatment, the amount of lost hair is 44% and average 56%.
  - 67% of volunteers observed a reduction in hair loss.
- Placebo group:
  - The importance of hair loss is average for 66% and close to 33% of them.
  - After 3 months of use of placebo lotion the amount of lost hair does not seem to vary (short for 33% and average 66%). No significant improvement is observed by volunteers.

2. Effectiveness lab test of Composition B

A composition according to the claimed invention was evaluated, i.e., Composition B (0.006% by weight of Octylbutyrate plus 0.006% by weight of glutaminpeptide, 0.0065% by weight of monomethylsilanol-hydroxyproline aspartate, 0.12% by weight of benzyl nicotinate, and 0.2% by weight of panthenol).

20 persons with hair loss problems (telogen effluvium) were selected.

Period	60 days, with applications every other day
Evaluations	At the beginning, after 7, 15, 30 and 60 days
TESTS	PULL TEST: Clinical Evaluation the strength of the hair pulling in Correspondence of 3 areas of the scalp hair.
	WASH TEST: hair counts lost after a wash in terms standard.

Results:

There was a statistically significant increase in the strength of hair strength (Pull test). This increase is already present after the first month of treatment (+76.4%) and continues to increase throughout the period of application to an increase of +141.2% after 60 days.

There was a statistically significant reduction of hair loss to Wash test. This reduction is already present

after the first month of treatment (-40.85%) and continues throughout the period of application to a reduction of 57.3% after 60 days.

% subjects who noted a decrease of hair loss:

after 30 days = 65%

after 60 days = 70%

Following are some percentages of subjects improved in various parameters monitored:

% of the subject with ameliorations PULL TEST

after 30 days = 55%

after 60 days = 85%

% of the subject with ameliorations WASH TEST

after 30 days = 90%

after 60 days = 95%

3. Comparison of effects on hair loss using Composition A and Composition B in a topical lotion

Results of subjective evaluation, or % of subjects in each sample which noted a decrease of hair loss:

	After 30 days	After 60 days	After 90 days
Composition A			67%
Composition B	65%	70%	

The table shows clearly that the composition B (of the formulation of the claimed invention) achieves anti-hair

loss effectiveness higher than that obtained with the use of composition A(solely Octylbutyrate + Glutaminpeptide), plus some details that validate the effectiveness of exceeds of the wording:

	Composition A	Composition B
Mode of application	Daily	**Every other day**
Positive results	After 90 days	**After 30 days**
Max % of subject with ameliorations	67% after 90 days	**70% after 60 days**

• Results on the decrease of lost hair (typically the hair in telogen)

Comparison of results on the reduction of hair in the telogen phase determined by electronic counts (Composition A) and the Wash Test (Composition B); methodologies for the determination are different but the objective is the same.

	After 30 days	After 60 days	After 90 days
Composition A			**-29.7%** reduction in telogen hair
Composition B	**-40.85%** % decrease in the loss of hair to wash test (loss in telogen hair) **90%** percentage of subjects improved to wash test **76.4%** increase % of the strength of the hair to pull test **55%** Of the subjects had an amelioration to pull test	**-57%** % decrease in the loss of hair to wash test (loss in telogen hair) **95%** percentage of subjects improved to wash test **141.2%** increase % of the strength of the hair to pull test **85%** Of the subjects had an amelioration to pull test	

4. **Conclusions**

Assessing the following parameters:

- % subjects who noted a decrease of the loss of hair
- % of subjects improved to PULL TEST and to WASH TEST (expression of the amount of hair in telogen)
- % increase in resistance and % decrease in the hair loss (linked to hair lost in telogen)

Based on the above, it is believed that the comparison of the results obtained clearly show that the composition B, which corresponds to the subject matter of the claims (a composition comprising Octylbutyrate plus glutaminpeptide, monomethylsilanol-hydroxyproline aspartate, benzyl nicotinate, and panthenol) proves a superior efficacy than the composition A, which is lotion containing only Octylbutyrate and Glutaminpeptide.

I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Dr. Daniela MONTANARI

14. 10. 2009
Date